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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IMPAX LABORATORIES, INC.,

Plaintiff,

V.

ACTAVIS LABORATORIES FL, INC. and  
ACTAVIS PHARMA INC.,

Defendants.

Civil Action No. 15-6934 (SRC)(CLW)

Motion Day: May 16, 2016

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF IMPAX LABORATORIES,  
INC.'S MOTION TO STAY PROCEEDINGS WITH RESPECT TO  
U.S. PATENT NO. 7,094,427**

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## I. INTRODUCTION

Plaintiff Impax Laboratories, Inc. moves this Court to stay proceedings in this case relating to U. S. Patent No. 7,094,427 (the “’427 Patent”)—one of six patents forming the basis of Impax’s lawsuit against Defendants Actavis Laboratories FL, Inc. and Actavis Pharma Inc.—pending the outcome of the reexamination of that patent by the United States Patent and Trademark Office (“PTO”). This reexamination was commenced three years ago and is nearing completion, with final argument in the reexamination appeal at the PTO recently set for June 1, 2016. This motion seeks to stay the proceedings only with respect to the ’427 Patent, and only until completion of the ’427 Patent reexamination proceedings at the PTO.

In the parties’ Proposed Joint Discovery Plan filed in January, the issue of the reexamination and its potential impact on the litigation of the ’427 Patent was brought to the Court’s attention. Indeed, it was Defendants who first broached the topic of staying the proceedings with respect to the ’427 Patent, prior to submission of the Proposed Joint Discovery Plan, wherein the parties noted that they were “in the process of discussing a course of action with respect to the ’427 patent . . . [and] expect[ed] to separately make a submission to the Court regarding the ’427 patent.” (D.I. 32 at 5). Given the delayed scheduling of the reexamination appeal argument and concomitant delay in final resolution, it is now evident that the reexamination proceeding will not be completed before at least Impax’s preliminary contentions are due to be served. Although Impax is hopeful that the PTO could issue a decision shortly after oral argument—and thus the stay would be brief and not impact *Markman* or other future dates—there is no definitive timetable for a final decision. In light of these circumstances, Impax respectfully suggests that it is prudent to temporarily stay proceedings with respect to the ’427 Patent to determine what (if anything) emerges from the reexamination to be litigated.

Impax has abandoned pursuit of the claims of the '427 Patent in their originally-issued form, and thus if and when the '427 Patent emerges from reexamination it will do so with meaningfully-amended claims. Moreover, any amended claims that emerge will not be effective outside of the PTO proceedings until the reexamination is concluded. Defendants acknowledge as much, and have provided preliminary contentions that only address the claims of the '427 Patent as originally issued—claims that have been cancelled or amended during the reexamination proceeding—and do *not* address any of the amended claims that might emerge from the reexamination. Moreover, Defendants have reiterated that they will serve supplemental contentions if and when amended claims emerge from the reexamination, consistent with their statement “reserve[ing] all rights with respect to any amendment or new claims that may emerge from the pending reexamination of the '427 patent.” Defendants’ Preliminary Invalidity Contentions at 13. Impax’s responses to Defendants’ contentions—pertaining to the effectively abandoned claims that are certain *not* to survive the reexamination proceeding—are due on June 3, 2016. Under the circumstances, Impax respectfully submits that it would be wasteful to proceed with litigating claims of the '427 Patent when such efforts will necessarily be moot, because either (1) nothing survives the reexamination, or (2) all work will have to be repeated after the conclusion of the reexamination with respect to the claims that emerge.

Because this litigation is in the early stages, Defendants will not be unduly prejudiced by a stay. Indeed, this being a Hatch-Waxman case with a 30-month stay in place,<sup>1</sup> Defendants’

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<sup>1</sup> The Drug Price Competition and Patent Term Restoration Act of 1984, Publ. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355 and 360cc and 35 U.S.C. §§ 156 and 271) (the “Hatch-Waxman Act”) allows a manufacturer seeking to make a generic version of an approved drug to file an Abbreviated New Drug Application (ANDA) for the same drug that has been approved by the FDA or that is bioequivalent to an approved drug. The ANDA process imposes a certification requirement with respect to patents covering the drug that has been approved by the FDA, requiring the generic manufacturer to certify in its ANDA with

proposed generic product cannot be approved before the earlier of February 5, 2018 or such date when the Court resolves the patent issues surrounding Defendants' Abbreviated New Drug Application. A stay of proceedings with respect to the '427 Patent pending final outcome of the reexamination will avoid unnecessary and wasteful litigation and reduce the burden on the Court and the parties. It simply makes no sense for the Court and the parties to undergo the time and significant expense associated with litigating claims that have been cancelled or amended only to repeat the process with the amended claims once the reexamination is complete. Having recognized this, courts addressing motions to stay pending reexamination in Hatch-Waxman cases have consistently agreed that a stay is appropriate in these circumstances. Impax respectfully submits that a stay is warranted here as well.

## **II. FACTUAL BACKGROUND**

Impax is a pioneer and leader in the development of drugs for the treatment of Parkinson's disease. Impax's drug RYTARY® was one of the first drugs of its kind formulated uniquely to address some long-standing and well-known shortcomings with preexisting Parkinson's disease therapies. In recognition of Impax's innovative work, the PTO issued several patents relating to the RYTARY® formulation and its uses. Six of those patents, including the '427 Patent, are the subject of the present litigation. The five asserted patents other than the '427

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respect to each patent that has not expired that the patent is invalid or will not be infringed by the marketing of the proposed ANDA product. This is known as a Paragraph IV certification. The filing of an ANDA before the expiration of a patent is an act of infringement, and under the statutory scheme, a brand name drug manufacturer who receives notice of a Paragraph IV certification has 45 days from receipt of the notice to initiate litigation for patent infringement in district court. If the patent owner timely files suit, the FDA is statutorily precluded from approving the ANDA until the date the court determines the invalidity or non-infringement of the challenged patent, the date the patent expires, or 30 months from the date the patent holder receives notice of the Paragraph IV certification.

Patent all share the same inventors, priority dates, and specification; the '427 Patent is unrelated to those five and has a different set of inventors, priority date, and specification.

The '427 Patent is currently involved in a PTO reexamination proceeding that commenced over three years ago at the request of a third party. None of the originally issued claims of the '427 Patent remain in the reexamination; rather, all of the originally issued claims have been amended or cancelled during the reexamination proceeding and the amended claims stand finally rejected as anticipated and/or obvious in view of the Licht<sup>2</sup> and Rubin<sup>3</sup> references. As permitted by PTO procedure, Impax has appealed the rejection to the Patent Trial and Appeal Board. Impax's appeal has been fully briefed as of May 22, 2015, and an oral argument has recently been scheduled for June 1, 2016. Should the PTAB affirm the Examiner's rejection of the amended claims, that decision is appealable to the Federal Circuit.

Defendants have filed an ANDA seeking approval from the FDA to market a generic version of Impax's innovative RYTARY<sup>®</sup> drug prior to the expiration of Impax's patents covering same. While Defendants could have certified to the FDA that they will not market their proposed generic version of RYTARY<sup>®</sup> until the expiration of the Impax patents, Defendants chose to challenge all six patents, certifying that the patents are invalid or will not be infringed by Defendants' proposed ANDA product. Thus, Plaintiff was left with no choice but to enforce its intellectual property rights by bringing suit or to tolerate Defendants' infringement of Plaintiff's intellectual property rights and allow a generic version of the innovative RYTARY<sup>®</sup> medicine on the market. Under Hatch-Waxman, it is an act of infringement to file an ANDA and the NDA holder of the reference listed drug is required to file suit no later than 45 days of receipt

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<sup>2</sup> U.S. Pat. Pub. No. 2003/0147957

<sup>3</sup> WO 00/15197, also published as U.S. Pat. No. 6,238,699.



of an ANDA filer's Paragraph IV notice letter in order to obtain the statutory 30-month stay allowing the district court to resolve the patent issues in an orderly fashion prior to any unauthorized launch by a generic company. This statutory framework resulted in Impax timely filing the instant lawsuit. Thus, a 30-month stay is in place and the FDA is statutorily prohibited from approving Defendants' ANDA prior to February 5, 2018—the expiration of the stay—or upon the resolution of the patent issues by this Court, whichever is earlier.

Actavis has served its preliminary non-infringement and invalidity contentions, arguing, among other things, that the '427 Patent is invalid as anticipated and/or obvious over the same Licht and Rubin references being considered by the PTO during the reexamination proceeding. Plaintiff's responses to Defendants' preliminary contentions are due on June 3, 2016. Claim construction discovery is scheduled to be completed on August 19, 2016, with a *Markman* hearing tentatively planned for November or December of this year, based on the availability and convenience of the Court. No depositions have been taken in this action; expert discovery has not commenced; and no trial date has been set.

### **III. THE COURT SHOULD STAY THE PROCEEDINGS WITH RESPECT TO THE '427 PATENT**

It is well-established that “the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936). As such, “the decision to stay a patent case in which the PTO has granted a request to reexamine the patent-in-suit rests within the sound discretion of the district court.” *EI Du Pont De Nemours & Co. v. MacDermid Printing Solutions, LLC*, No. 10-cv-3409 (MLC), 2012 WL 2995182, at \*2 (D.N.J. July 23, 2012) (citing *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27

(Fed. Cir. 1988) (citation omitted). The advantages of a stay pending completion of a reexamination proceeding include:

(1) a review of all prior art presented to a court by the PTO, with its particular expertise; (2) the potential alleviation of numerous discovery problems relating to prior art by PTO examination; (3) the potential dismissal of a civil action should invalidity of a patent be found by the PTO; (4) encouragement to settle based upon the outcome of the PTO reexamination; (5) an admissible record at trial from the PTO proceedings which would reduce the complexity and length of the litigation; (6) a reduction of issues, defenses and evidence during pre-trial conferences; and (7) a reduction of costs for the parties and a court.

*Brass Smit, LLC v. RPI Indus., Inc.*, No. 09-cv-06344 (NLH/JS), 2010 WL 4444717, at \*2 (D.N.J. Nov. 1, 2010) (internal quotation marks and citations omitted). “While courts weigh the costs and benefits associated with granting a stay pending reexamination of a patent ‘courts have noted that granting a stay pending reexamination is favored.’” *Id.*; see also *ICI Uniqema, Inc. v. Kobo Prods., Inc.*, No. 06–2943(JAP), 2009 WL 4034829, at \*1 (D.N.J. Nov. 20, 2009) (citing *Alltech, Inc. v. Cenzone Tech, Inc.*, No. 06-cv-0153(JM), 2007 WL 935516 (S.D.Cal. March 21, 2007) (“[t]here is a liberal policy in favor of granting motions to stay proceedings pending the outcome of reexamination proceedings”); *Cross Atl. Capital Partners, Inc. v. Facebook, Inc.*, No. 07-cv-2768(JRP), 2008 WL 3889539, at \*1 (E.D.Pa. Aug. 18, 2008) (“Stays are particularly appropriate when the reexamination result might assist the court in making a validity determination or would eliminate the need to make an infringement determination.”)

To determine whether a stay is appropriate, courts consider: “(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set.” *Stryker Trauma S.A. v. Synthes (USA)*, No. 01-cv-3879(JLL), 2008 WL 877848, \*1 (D.N.J. March 28, 2008) (quoting *Xerox Corp. v. 3Com*

*Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999)). Here, all factors favor this Court exercising its discretion to stay proceedings directed to the '427 Patent pending resolution of the reexamination by the PTO.

**A. Defendants Will Not Be Prejudiced by a Stay**

Defendants will not be prejudiced by a stay. “[D]elay inherent in the reexamination process is itself insufficient to establish prejudice.” *EI Du Pont de Nemours*, 2012 WL 2995182, at \*4; *see also Oy Ajat, Ltd. v. Vatech Am., Inc.*, No. 10-cv-4875(PGS), 2012 WL 1067900, \*21 (D.N.J. March 29, 2012); *Brass Smith, LLC v. RPI Indus., Inc.*, No. 09-cv-6344 (NLH/JS), 2010 WL 4444717, \*4 (D.N.J. Nov. 1, 2010); *ICI Uniqema*, 2009 WL 4034829, at \*2. Moreover, as Defendants are not and cannot presently market their proposed ANDA product, Impax and Defendants are not direct competitors with respect to the product at issue in the instant case. *See Mondis Tech. Ltd. v. LG Elec. Inc.*, No. 15-cv-4431 (SRC)(CRW), 2015 WL 7012747, at \*6 (D.N.J. Nov. 12, 2015) (finding no harm to a party that “is not selling or actively licensing goods or services related to the patents-at-issue”). Nor can Defendants lose market share during a stay because they have no market share to lose. And although Actavis has submitted its application to the FDA requesting approval to sell its proposed generic product, there is no certainty whether, or when, the FDA will approve that application. Indeed, the FDA cannot approve Defendants’ ANDA until February 5, 2018 (the expiration of the 30-month stay) unless this Court were to resolve the patent issues before that time, and the agency may delay the approval further at its discretion.

To the extent Defendants argue that they will suffer prejudice because they will not have final resolution on the '427 Patent prior to the expiration of the 30-month stay, courts have repeatedly found this argument unconvincing. *See, e.g., CIMA Labs Inc. v. Actavis Group HF*, Civ. Nos. 07-893 (DRD), 06-1970 (DRD), 06-1999 (DRD), 2007 WL 1672229, at \*10 (D.N.J.

June 7, 2007) (granting motion to stay pending resolution of reexamination in Hatch-Waxman litigation); *CIMA Labs Inc. v. Mylan Pharms., Inc.*, No. 10-cv-625 (LPS), 2011 WL 1479062, at \*4 (D. Del. Apr. 18, 2011) (finding that potential prejudice to Hatch-Waxman defendant based on its inability to reach an early-non-appealable resolution of the patent issues is too speculative to counsel against a stay); *Genzyme Corp. v. Cobreck, Pharms., Inc.*, No. 10-cv-00112, 2011 WL 686807, at \*5 (N.D. Ill. Feb. 17, 2011) (finding that “the likely potential outcomes set in motion by the stay are too speculative to support a finding of undue prejudice to [Hatch-Waxman] Defendant.”). Likewise here, any potential harm to Defendants is speculative at best as any prejudice depends on at least the following conditions being met: that the accused product does not infringe the patents-in suit—a finding that is not possible to make with respect to the ’427 Patent until the conclusion of the reexamination; that the instant litigation (including any appeal) can and will be resolved prior to the expiration of the 30-month stay; and that Defendants’ ANDA will be approved before the expiration of the stay. If any of these assumptions fail, which is quite possible, Actavis will suffer no prejudice. *See Mylan Pharms., Inc.*, 2011 WL 1479062 at \*4.

Nor would any delay in resolving issues related to the ’427 Patent prevent Defendants from launching their proposed ANDA product at the end of the stay, even if issues related to the ’427 Patent remain unresolved. Put simply, if Defendants are confident in their positions, once they receive FDA approval and absent a preliminary injunction of this Court based on a finding of likely success on the merits in favor of Impax, Defendants will be free to launch their product. That they may later be found to have infringed the reexamined ’427 Patent is of no consequence in the instant analysis for “[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the

business so elected.” *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986).

Further, Impax has not unduly delayed the instant proceedings or sought to use the reexamination proceeding in a dilatory way. To the contrary, the reexamination proceeding was filed by a third party over three years before the instant litigation commenced. Once it filed the instant case, Impax has proceeded quickly and efficiently, in all cases aiming to move the matter forward without unnecessarily wasting the Court’s and the parties’ resources. Accordingly, Impax cannot be accused of filing the present stay motion or the reexamination proceeding as a dilatory tactic, and the first factor heavily weighs in favor of this Court exercising its discretion to stay proceedings directed to the ’427 Patent.

**B. A Stay Will Significantly Simplify The Issues In This Case**

A stay pending reexamination will significantly simplify issues in the case. Specifically, all of the issued claims of the ’427 Patent have been amended and cancelled in the reexamination, and all of the amended claims stand finally rejected. Thus, if the ’427 Patent emerges from reexamination at all, it will do so with meaningfully different claims. Although the PTO will treat the amendments to the ’427 Patent as entered for the purpose of the pending appeal, the amendments will not take effect outside of the PTO until conclusion of the reexamination proceedings, *i.e.*, when a reexamination certificate is issued. 37 C.F.R. § 1.530(k). In other words, at this time, the ’427 Patent is presently “at issue” in this litigation in its unamended form, not in the amended form that ultimately would exist after a successful resolution of the reexamination proceedings.

The amendment of all claims of the ’427 Patent favors a stay. The parties should litigate, and the Court should adjudicate, the ’427 Patent in the form it will have when it ultimately emerges from the reexamination proceedings. The futility of moving forward with the issued

claims now—claims that will not survive reexamination—is readily apparent. Indeed, as Defendants have recognized, if and when the '427 Patent emerges from the reexamination in amended form, contentions will need to be supplemented, and (in the event of a substantial further delay) a second *Markman* hearing may be necessary to address issues resulting from the reexamination amendments. Expert submissions will similarly need to be redone to address new issues. Under similar circumstances, courts have routinely explained that, where the PTO is likely to modify the patent during a co-pending reexamination, staying the case conserves the parties' and the court's resources. *See, e.g., ICI Uniqema, Inc.*, 2009 WL 4034829, at \*2 (“A stay would prevent resources from being expended on invalid or amended claims.”); *see also Indus. Tech. Research Inst.*, 2013 WL 5180108, at \*8 (finding that a stay would simplify litigation where “[c]laim amendment isn’t merely possible; it is guaranteed”). Likewise, here, it is not merely possible that the '427 Patent will emerge—if at all—in an amended form; it is guaranteed.

The Defendants contend that the issued and amended claims are not so different that the Court's rulings on the issued claims would be rendered moot by the claim amendments. In effect, the Defendants argue that the Court can, for example, construe the issued claims, and carry over those rulings to the amended claims, only addressing any additional issues in a subsequent *Markman* hearing. But that is tantamount to asking the Court to construe the claims based on an imperfect and incomplete record. It would be wasteful for the Court to adjudicate the patent without the benefit of the PTO's completed reexamination record, particularly where, as here, the arguments presented by the Defendants mirror those addressed by the PTO in the reexamination proceeding and rely on the same prior art references—Licht and Rubin. *See, e.g., Mondis Techs.*, 2015 WL 7012747, at \*7 (noting that a stay would allow the court to benefit from “the full

prosecution history of all asserted patents” and “the PTO’s analysis of prior art and the scope of the asserted claims.”). If the ’427 Patent emerges from the reexamination, this Court will be able to consider the PTO’s complete analysis when ruling on any similar issues in this litigation. “[E]ven if the reexamination d[oes] not lead to claim amendment or cancellation, it could still provide valuable analysis to the district court.” *EI Du Pont De Nemours*, 2012 WL 2995182, at \*7 (quoting *ICI Uniquema*, 2009 WL 4034829, at \*2).

Moreover, the ’427 Patent is the only unrelated patent in the instant case. The remaining five patents are of the same family, and share the same inventors and specification. Furthermore, the reexamination of the ’427 Patent has been underway for nearly four years. Although Impax is convinced of the validity of the patent claims and of the merits of its positions, all issued claims of the ’427 Patent have been amended during the reexamination and the amended claims currently stand finally rejected by the PTO, with a PTAB appeal pending. It is possible that Impax may not ultimately prevail or that the claims may again be amended before the reexamination concludes. Thus, any of the infringement claims under the ’427 Patent as issued that the Court may address at this time will be moot at the conclusion of the reexamination. *See, e.g., Indus. Tech. Research Inst. v. LG Elecs. Inc.*, No. 12-cv-949 (ES), 2013 WL 5180108, at \*8 (D.N.J. Sept. 12, 2013) (granting patentee’s request for a stay at a time when all asserted claims were rejected in reexamination); *Mondis Techs.*, 2015 WL 7012747, at \*7 (finding that a stay is favored where “the PTO may dispose of one or more of the claims raised in this case, creating the possibility that this case may be simplified without further effort from this Court.”)

Under these circumstances, it would be futile to direct pretrial activities toward the ’427 Patent as it currently exists. It would also unnecessarily complicate the proceedings to begin litigation of the ’427 Patent in its current form, only to change directions after the PTO

completes reexamination of the patent. Indeed, absent a stay, the Court and the parties risk expending substantial resources litigating issues that *will* be affected and potentially mooted by the reexamination proceedings. And, to the extent this Court resolves the issues before the PTO completes reexamination, any appeal of this Court's decision would either be moot (if the claims are finally cancelled), or based on an incomplete record (if the PTO confirms the amended claims). Indeed, Actavis has acknowledged the futility of litigating the issued '427 claims, noting in its preliminary invalidity contentions that it "reserves all rights with respect to any amended or new claims that may emerge from the pending reexamination of the '427 patent." (Defendants' Preliminary Invalidity Contentions at 13). As such, "[a] stay would prevent resources from being expended on invalid or amended claims." *ICI Uniquema*, 2009 WL 4034829, at \*2.

Because a stay pending reexamination would significantly simplify issues relating to the '427 Patent in this litigation and avoid wasteful litigation, this Court should grant Impax's motion to stay.

### **C. The Early Stage Of This Litigation Favors A Stay**

The fact that this case is in its infancy strongly favors a stay. Discovery has just begun, and the parties have not engaged in any depositions, or claim construction efforts with respect to the '427 Patent, and a trial date has not been set. Indeed, this case is at a far earlier stage than most cases where the early stage-of-the-case has been found to favor a stay. *See, e.g., El Du Pont De Nemours*, 2012 WL 2995182, at \*7-8. The overwhelming majority of time and expense associated with litigating the '427 Patent is yet to come. The fact that Impax files this motion near the outset of the case strongly favors granting a stay.

## **IV. CONCLUSION**

This case is in its early stages. All claims of the '427 Patent have been amended during the reexamination proceeding and the amended claims currently stand finally rejected by the



PTO, with a PTAB appeal pending. If and when any claims of the '427 Patent emerge from the reexamination, they will emerge in amended form and thus necessitate the parties to re-do any litigation activities that are conducted in the meantime. Thus, Impax respectfully submits that this Court should stay the case with respect to the '427 Patent.

Dated: April 19, 2016

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**CERTIFICATION OF SERVICE**

I hereby certify that on this date I served the foregoing Memorandum of Law and accompanying Notice of Motion and proposed Order upon all counsel of record via the Court's ECF system and electronic mail.

Dated: April 19, 2016

/s/ Michael E. Patunas